DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

7

d1590b

December 4, 1996

Ref: 97-DAL-WL-10

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Anthony G. Roth, President
Performance Nutrition, Inc.
3230 Commander Drive
Carrollton, Texas 75006

WARNING LETTER

Dear Mr. Roth:

This letter is in reference to your firm's marketing and distribution of a product which is labeled to aid in the disease conditions known as Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD). Your promotional brochure (labeling) titled, "A safe effective approach to nutrition," makes therapeutic claims for KidsPlex Jr which cause the product to be a drug [201(g)] of the Federal Food, Drug and Cosmetic Act (the Act).

Objectionable claims include, but are not limited to the following:

> "KidsPlex Jr., because of its fortification with inhibitory amino acids, has the potential to help children with Attention Deficit Hyperactivity Disorder (ADHD)."
>
> "One of these, KidsPlex Jr., is a safe, effective and powerful nutritional supplement, designed specifically for today's kids-on-the-go, that may, when combined with other therapies prescribed by medical professionals, show positive results for people exhibiting hyperkinesis, or Attention Deficit Hyperactivity Disorder."

In addition, the immediate product label and representations of the immediate product label for KidsPlex Jr., include prominent reference to ADHD or ADD.

Further, a press release issued by David E. Wynne, your representative, describes KidsPlex Jr. to be "...a safe, effective approach that may bring relief from the over prescription of the mind altering drug" (referring to Ritalin®).

In 1994, Congress passed and President Clinton signed the Dietary Supplement Health and Education Act (DSHEA). This Act which defines dietary supplements and dietary ingredients establishes a new framework for assuring safety; outlines guidelines for literature display; and provides guidance for literature displayed where supplements are sold. While DSHEA carefully describes the use of certain statements in the labeling of dietary supplements, these statements may not include claims for the diagnosis, prevention, mitigation, treatment, or cure of a specific disease. Products making such disease claims are considered drugs, not dietary supplements.

KidsPlex Jr. is a "new drug" [§ 201(p)]. This is based on claims for the treatment of specific disease conditions, Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder, made in the labeling and the lack of evidence that this product is generally recognized as safe and effective for its intended use. Therefore, it may not be legally marketed in this country as it is not the subject of an approved New Drug Application (§ 505 of the Act).

This drug is misbranded because its labeling fails to bear adequate directions for use [§ 502(f)(1)] and because the labeling is false and misleading, since it represents and suggests that there is evidence that this product is safe and effective for its intended use and this is not the case [§ 502(a)].

For your information, we are aware of a brochure titled "An Open Letter from One CSF Survivor" which appears to promote both KidsPlex Jr. and Plex for the treatment or cure of Chronic Fatigue Syndrome (CSF). CSF is a disease and claims for the treatment of CSF represent drug claims.

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working day, state the reason for the

delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

Elaine R. Crosby

Elaine R. Crosby
Acting District Director

ERC:RRR:jab